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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,909	11/17/2000	Ronald D. Flannagan	35718/204664	5613

29122 7590 11/17/2003

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/715,909

Applicant(s)
Flannagan et al

Examiner
Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 9, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 8, 10-18, and 26-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 10-18, 26-29, and 32-36 is/are rejected.
- 7) ☒ Claim(s) 30 and 31 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11115 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/09/03 has been entered.
2. The amendment filed 7/09/03 has been entered.
3. The rejection of claims 1-3, 7-8, 10-18 & 32 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to recitation of structural and functional limitations for what constitutes the essential component of the instant invention (i.e., as it relates to SEQ ID NO:1 or 2).
4. The rejection of claims 1-3, 7-8 & 10-16 under 35 U.S.C. 102(b) as being anticipated by Bulla et al. (U.S. Patent 5,693,491) is withdrawn due to the amendment of the claims.
5. Applicants' arguments filed 7/09/03 have already been considered in the Advisory Action but were not found persuasive.

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6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 30-31 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 1-3, 7-8, 10-18, 26-29 & 32-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed, for the reason made of record in Paper Nos: 10 (mailed 2/13/02), 13 (mailed 10/18/02) & 16 (mailed 4/07/03), and as follows.

Applicants argue on pages 9-10 of the response that the claims have been amended to "consisting of at least 150 contiguous residues of... SEQ ID NO:2, wherein said polypeptide comprises the ligand binding site of SEQ ID NO:2". In contrast, page 35 of the specification states that "[t]he CryIA binding site is encoded by residues 4038-4547", which is 170 (510/3) amino acid residues, and not 150 contiguous residues, as recited in claim 7g, which therefore, provides no written description for those 20 other required encoded amino acids; nor in general for this generic nucleotide sequence that merely requires "comprising the ligand binding site of SEQ ID NO:2" (i.e, as it relates to claim 1g). As previously made of record, no allelic variants

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are described within the specification. Nor are any nucleic acid molecules that encompass different species of the *Lepidopteran* order/genus described (e.g., as it relates to claims 1 & 26-29). Again, the claims still encompass undescribed molecules not limited to encoding the open reading frame depicted as SEQ ID NO:2, nor limited to any described *Ostrinia nubilalis* receptor nucleic acid molecule. In contrast, the claims encompass unknown and undescribed heterologous sequences “of interest...” fused to polypeptides that merely “consist of at least”/comprise “150 contiguous amino acids of SEQ ID NO:2”, etc., which include unknown and undescribed encoded “toxin receptors” (e.g., as it relates to claim 8). Thus, the written description requirements under 35 U.S.C. 112, first paragraph are not reasonably met by the current claims; consistent with that held by the courts in *Fiers v. Revel* and *Univ. California v. Eli Lilly and Co.* previously made of record.

In summary, the specification describes the sole *Lepidopteran* insect receptor nucleic acid from the species *Ostrinia nubilalis* of SEQ ID NO:1 (see page 3 of the specification). No other species of *Lepidopteran* insect receptor nucleic acids are described by which one of skill in the art could reasonably visualize what structurally constitutes this claimed genus of insect nucleic acid sequences. Thus, Applicants are clearly not in possession of the claimed genus of *Lepidopteran* insect receptor nucleic acid molecules claimed, for the reasons made of record.

Applicants are again directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999 (i.e., see Examples 6, 11 and especially Example 17).

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9. Claims 7-8 & 33-36 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because it remains ambiguous what metes and bounds constitute “at least one polypeptide *of interest*”, which is a relative term that defines nothing by itself; thereby, remaining indefinite.

Applicants argue on page 13 of the response that “the specification provides guidance regarding the recited polypeptides of interest on line 10 of page 21 through line 16 of page 22”. However, “guidance” is an issue for consideration under 112 first paragraph, whereas pages 21-22 merely provide a putative open-ended definition for what is intended to be encompassed by the claims. In contrast, the pending issue is that the recitation of a relative term, which defines nothing, is indefinite. Moreover, although Applicants are permitted to be their own lexicographer, no term may be given meaning repugnant to the usual meaning of the term (see MPEP 608.01 (o)); especially when the specification fails to specifically define the metes and bounds this term otherwise encompasses. Therefore, Applicants’ arguments are not persuasive.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.

November 13, 2003

per sig